Application No. 10/576,182 Paper Dated: February 8, 2010

In Reply to USPTO Correspondence of November 6, 2009

Attorney Docket No. 4647-061111

# **AMENDMENTS TO THE DRAWINGS**

The attached sheet of drawings includes changes to Fig. 1. This sheet, which includes Fig. 1, replaces the original sheet including Fig. 1. An Annotated Sheet showing the changes to Fig. 1 is also attached hereto.

Attachment: Replacement Sheet

**Annotated Sheet Showing Changes** 

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### REMARKS

### I. <u>Introduction</u>

The Office Action, dated November 6, 2009, has been reviewed and the Examiner's comments carefully considered. The present Amendment amends claims 1, 9, 11, 22, 36, 54, 65, 67, and 69-72 in accordance with the originally-filed specification. No new matter has been added. In addition, the present amendment cancels claims 7 and 38. Accordingly, claims 1-5, 8, 9, 11, 18-20, 22, 23, 25, 31, 32, 36, 37, 39, 41, 43, 44, 46, 53-55, 65-67, and 69-72 are currently pending in this application, and claims 1, 36, and 69-72 are in independent form.

#### II. Interview of December 21, 2009

The Applicants would like to thank Examiner Perungavoor for the courtesies extended to the Applicants' representative during the telephonic interview of December 21, 2009. During the interview, the Examiner's refusal to enter the amendments to the specification and drawings set forth in the Amendment of October 5, 2009 was discussed. The Examiner indicated that these amendments would be entered if FIG. 1 was further amended to remove the line coupling the mechanical loading mechanism (30) to the culture wells (12). Accordingly, FIG. 1 has been amended pursuant to the Examiner's suggestion. In addition, the rejections of the claims under 35 U.S.C. §112, first paragraph, were discussed. More specifically, the Applicants' representative pointed out the areas in the specification where support for the amendments to claims of October 5, 2009 could be found. The Examiner then suggested amending independent claims 1, 36, and 69-72 as set forth hereinabove to more clearly define the present invention. In addition, the Examiner recommended placing on the record where support for the current claim language could be found in the specification. Finally, the Examiner indicated that the above amendments to the claims, along with a description of where support for the claim language could be found in the specification, would overcome the rejections under 35 U.S.C. §112, first paragraph as set forth in the Office Action of November 6, 2009 and place the application in condition for allowance.

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## III. Specification Objection

The Examiner indicated that the specification amendment filed on October 5, 2009 has not been entered because it is considered new matter. During the interview of December 21, 2009, it was explained to the Examiner that the only change to the specification was to add a reference numeral after the language "mechanical loading mechanism" that corresponded with the reference numeral for the mechanical loading mechanism added to FIG. 1. The Examiner agreed that this was not new matter. Accordingly, entry of the specification amendment filed on October 5, 2009 is respectfully requested.

### IV. Drawing Objection

The Examiner indicated that the drawing amendment filed on October 5, 2009 has not been entered because it is considered new matter. During the interview of December 21, 2009, it was explained to the Examiner that the only change to FIG. 1 of the drawing amendment was to add a block for the mechanical loading mechanism as clearly described in paragraph [0040] of the specification. The Examiner indicated that the amendment to FIG. 1 as set forth in the attached Replacement Sheet overcomes this objection and will be entered. Accordingly, entry of the attached Replacement Sheet that includes amendments to FIG. 1 is respectfully requested.

# V. 35 U.S.C. §112, First Paragraph Rejections

Claims 1-5, 7-9, 11, 18-20, 22, 23, 25, 31, 32, 36-39, 41, 43, 44, 46, 53-55, 65-67, and 69-72 stand rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. More specifically, the Examiner contends that the language "determining at least one of the following: matrix organization, matrix compaction, matrix contraction, response to loading, or any combination thereof" in claims 1, 36, and 69 and the language "determining a response to the applied load" in claims 70-72 does not have support in the application as originally filed.

### A. Claim Amendments

Initially, the Applicants would like to note that independent claims 1, 36, and 69-72 have been amended hereinabove to more clearly define the present invention. These Application No. 10/576,182

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amendments were suggested by the Examiner during the interview of December 21, 2009. The Examiner indicated that these amendments, along with the following remarks, would overcome the written description rejections set forth in the Office Action of November 6, 2009.

### B. Support in the Specification as originally filed

In addition, the Applicants would like to note that the language "determining at least one of the following: matrix organization, matrix compaction, matrix contraction, response to loading, or any combination thereof' is supported by the description provided in the specification as originally filed. For instance, paragraph [0007] of the originally-filed specification provides that "[a]ccording to the prior art and with respect to tissue, engineered constructs, and genetic material generally, measurements of matrix compaction, organization, contraction and other parameters are performed manually by periodically removing the culture plates from the controlled environment, e.g., inside an incubator apparatus, to access an external imaging device, such as a camera or a scanner" (emphasis added). This paragraph further provides that "it is preferable to analyze and monitor these constructs, without repeatedly exposing these constructs to dramatic environmental changes." In addition, the specification further provides that the system (10) can analyze data for determining one or more desired parameters within the culture well (12) or culture well area of interest (see paragraph [0038]). Accordingly, one of ordinary skill in the art would recognize from the description provided in the originally filed specification that the parameters discussed in paragraph [0038] and provided in the claims would correspond to matrix compaction, organization, and contraction as described in paragraph [0007]. This is further supported by the description in paragraph [0047] that describes that the well area of interest can be expanded, contracted, and/or manipulated and then an image of the well can be obtained with an imaging device. Finally, support for the requirement of a loading mechanism for providing a load to the sample can be found in paragraph [0040] of the specification as originally filed.

Accordingly, the language provided in amended independent claims 1, 36, and 69-72 is fully supported by the specification as originally filed and is not new matter. The Applicants respectfully request reconsideration and withdrawal of these rejections.

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## VI. 35 U.S.C. §112, Second Paragraph Rejections

Claims 7 and 38 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicants regard as the invention. Claims 7 and 38 have been cancelled by the present Amendment, thereby rendering the rejection of these claims moot. Accordingly, withdrawal of this rejection is respectfully requested.

### VII. Conclusion

Based on the foregoing amendments and remarks, the Applicants respectfully request entry of the above amendments and allowance of pending claims 1-5, 8, 9, 11, 18-20, 22, 23, 25, 31, 32, 36, 37, 39, 41, 43, 44, 46, 53-55, 65-67, and 69-72. Should the Examiner have any questions or wish to discuss the application in further detail, the Examiner is invited to contact the Applicants' undersigned representative by telephone.

Respectfully submitted,

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